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10/576,030	04/13/2006	Masanori Yamaguchi	TOYA149001APC	2081

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EXAMINER

LAU, JONATHAN S

ART UNIT	PAPER NUMBER
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1623

NOTIFICATION DATE	DELIVERY MODE
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06/23/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/576,030	Applicant(s) YAMAGUCHI ET AL.	
	Examiner Jonathan S. Lau	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-37, 39, 40 and 43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-37, 39, 40 and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is responsive to Applicant's Amendment and Remarks, filed 06 Mar 2009, in which claim 35 is amended to change the scope and breadth of the claim, claim 43 is amended to change dependency, and claims 41 and 42 are canceled.

This application is the national stage entry of PCT/JP04/15174, filed 14 Oct 2004; and claims benefit of foreign priority documents JAPAN 2003-353490, filed 14 Oct 2003; JAPAN 2003-353491, filed 14 Oct 2003; JAPAN 2004-018128, filed 27 Jan 2004; and JAPAN 2004-194088, filed 30 Jun 2004; currently English language translations of said foreign priority documents are not of record.

Claims 35-37, 39, 40 and 43 are pending in the current application and examined on the merits herein.

Rejections Withdrawn

Applicant's Amendment, filed 06 Mar 2009, with respect to claims 35-37 and 39-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merck (DE 3405663, published 22 Aug 1985, provided by Applicant on IDS mailed 26 May 2006) in view of Weser (Structure and Bonding, vol. 2, 1967, p160-180, of record) in view of Weissbach (Journal of Organic Chemistry, 1958, 23, p329-330, provided by Applicant on IDS mailed 26 May 2006) has been fully considered and is persuasive, as claims 41 and 42 are canceled and Merck in view of Weser in view of Weissbach does not

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specifically teach the method comprising the first step of precipitating a scyllo-inositol/boric acid complex required by amended claim 35. Claims 36-37, 39, 40 and 43 depend from claim 35 and incorporate all limitations therein.

This rejection has been **withdrawn**.

The following are new grounds of rejection necessitated by Applicant's Amendment, filed 06 Mar 2009, in which claim 35 is amended to change the scope and breadth of the claim and claims 41 and 42 are canceled. Claims 36-37, 39, 40 and 43 depend from claim 35 and incorporate all limitations therein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Amended Claims 35-37, 39, 40 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merck (DE 3405663, published 22 Aug 1985, provided by Applicant on IDS mailed 26 May 2006) in view of Weissbach (Journal of Organic Chemistry, 1958, 23, p329-330, provided by Applicant on IDS mailed 26 May 2006) in view of Mopper (Analytical Biochemistry, 1978, 87, p162-168, cited in PTO-892) and in view of the Encyclopedia Britannica relied upon to show common knowledge in the art (entry for separation and purification, Encyclopedia Britannica Online, cited in PTO-892). Kiely et al. (Annals of the New York Academy of Sciences, 1969, 165(2), p559-563, cited in PTO-892) provides evidence of known inherent chemical properties. Sigma-Aldrich (Technical Information Bulletin AL-142, Sigma-Aldrich, of record) is provided as evidence of the composition of Amberlite MB-3 resin. As DE 3405663 is published in German, all citations of Merck herein refer to the machine translation of record and the translation of paragraphs 12-14 at page 2 provided by Applicant in Remarks filed 06 Mar 2009.

Merck discloses a procedure for the production of scyllo-inositol ("scyllo Inosit" from myo-inosose (page 1, paragraph 8). Merck discloses the procedure using the source of boric acid, sodium borohydride (page 2, paragraph 6). Merck discloses the procedure is known to produce borate from sodium borohydride (page 2, paragraph 12 provided by Applicant) Merck discloses acidifying the borohydride reduction product with 2N hydrochloric acid (page 2, paragraph 12 provided by Applicant), treating the complex of boron and scyllo-inositol with acid. Merck discloses separating the scyllo-inositol as crystals (page 2, paragraph 13 provided by Applicant), isolating and purifying

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the scyllo-inositol from the acid solution. Merck discloses filtration with a cation exchanger column (page 2, paragraph 12 provided by Applicant), or a strong acidic ion exchange resin. Merck discloses adding methanol to the concentrated aqueous filtered solution (page 2, paragraph 12 provided by Applicant) in order to crystallize the scyllo-inositol (page 2, paragraph 13 provided by Applicant).

Merck does not specifically disclose the first step of precipitating a scyllo-inositol/boric acid complex (instant claim 35). Merck does not specifically disclose the method wherein the amount of methanol is added in a volume 0.3 to 5 times the volume of the acid solution or adjusting the pH of the mixture to 8.0 to 11.0 (instant claim 35). Merck does not specifically disclose adjusting the pH of the mixture 9.0 to 10.0 (instant claim 37). Merck does not specifically disclose the method wherein the mixture contains myo-inositol and scyllo-inositol and is obtained by reducing scyllo-inosose (instant claim 39). Merck does not specifically disclose the method wherein method wherein the acidic solution is contacted with a strong acidic ion exchange resin and a strong basic ion exchange resin (instant claim 40). Merck does not specifically disclose the method wherein the amount of methanol is added in a volume 0.9 to 2 times the volume of the acid solution (instant claim 43).

Weissbach teaches scyllitol, or scyllo-inositol, is known to form a diborate complex with two borate moieties (page 329, right column, figure 1). Weissbach teaches reduction of scyllo-myo-inosose with sodium borohydride generates a mixture of scyllitol and myo-inositol from which the diborate of scyllitol precipitates (page 329, right column, paragraph 2). Kiely et al. provides evidence that the sodium salt of the

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diborate of scyllitol is well known to be highly insoluble (page 561, paragraph 3).

Weissbach teaches the diborate complex of scyllo-inositol is easier to separate from myo-inositol (page 329, left column, paragraph 3). Weissbach teaches the acidification of the complex (I) of scyllo-inositol and borate and the contacting of the solution with the resin Amberlite MB-3 (page 330, left column, paragraph 1), a mixture of strongly acidic and strongly basic resins as evidenced by Sigma-Aldrich (Sigma-Aldrich, page 4, section 5. Amberlite Monobed Resin).

Mopper teaches separation of sugar-borate complexes are well known in the art (abstract). Mopper teaches it is well known in the art that the said complexes are formed by treating the sugar with boric acid, H_3BO_3 , at a pH 8.63 (page 163, Paragraph Buffer) and teaches that optimization of parameters of concentration and pH are well known for the borate system (page 163, paragraph 1). Mopper teaches optimization of buffer pH and salinity in the field of separating of sugar-borate complexes is routine (page 166, paragraphs 2 and 3).

The Encyclopedia Britannica provides evidence that it is common knowledge in the art that separations based on equilibria are known for the same purpose of chemical separations (paragraph 1) and that ion exchange and absorption chromatography are known for the same purpose of as precipitation and crystallization as a separations method based on liquid-solid phase equilibria (Table 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Merck in view of Weissbach in view of Mopper and in view of the Encyclopedia Britannica relied upon to show common knowledge in the art. Both Merck

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and Weissbach are drawn to the product of reduction of myo-inosose with sodium borohydride. Both Weissbach and Mopper teach sugar-borate complexes are known to be useful for the separation of sugars, and Merck teaches the separation and purification of the sugar product. The Encyclopedia Britannica provides evidence that it is common knowledge in the art that separations based on equilibria are known for the same purpose of chemical separation and purification. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art.", see MPEP 2144.06. Analogously, it is *prima facie* obvious to combine two methods of separation based on liquid-solid phase equilibria that are common knowledge in the art in order form a third method of separation based on liquid-solid phase equilibria useful for the same purpose. Weissbach with evidence of Kiely et al. teaches the sodium salt of the diborate of scyllitol is well known to be highly insoluble, and Weissbach teaches the diborate of scyllitol may be separated as precipitate from the reduction of myo-inosose with sodium borohydride. One of ordinary skill in the art would be motivated to combine Merck in view of Weissbach in view of Mopper and in view of the Encyclopedia Britannica relied upon to show common knowledge in the art because Weissbach teaches the diborate complex of scyllo-inositol is easier to separate from myo-inositol and Mopper teaches formation of sugar-borate complexes is a well known process in the art for the separation of sugars. Mopper teaches that optimization of parameters of concentration and pH are well known for the

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borate system for separation of sugars. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical, see MPEP 2144.05 II.A.

Response to Applicant's Remarks:

Applicant's Remarks, filed 06 Mar 2009, have been fully considered and not found to be persuasive.

Applicant notes that Merck at page 2 paragraph 12 discloses the reaction of myo-inosose and sodium borohydride performed in methanol and notes that Merck does not disclose the formation of any precipitate in the reaction as required in the claims as amended. However, Weissbach teaches reduction of scyllo-myo-inosose with sodium borohydride generates a mixture of scyllitol and myo-inositol from which the diborate of scyllitol precipitates and Weissbach with evidence of Kiely et al. teaches the sodium salt of the diborate of scyllitol is well known to be highly insoluble. It is *prima facie* obvious to combine two methods of separation based on liquid-solid phase equilibria that are common knowledge in the art in order form a third method of separation based on liquid-solid phase equilibria useful for the same purpose of chemical separations and purification.

Conclusion

No claim is found to be allowable.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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